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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,554	09/28/2001	Bruce J. Holub	6580-262	2581

7590

04/09/2003

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

10

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,554

Applicant(s)

HOLUB ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,9-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-12, 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed 24 January 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 3, 6, 8 and 13 have been cancelled.
2. Claims 1, 5, 9, 14 and 16-18 have been amended.
3. Remarks drawn to rejections under 35 U.S.C. 112, 102 and 103.

Claims 1, 2, 4, 5, 7, 9, 10-12 and 14-20 are pending.

Claim Objections

Claims 5 and 7 are objected to because of the following informalities: Claims 5 and 7 are substantial duplicates. One of them has to be cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 20 are drawn to a composition according to claims 5 and 7 respectively wherein the kidney disease is polycystic kidney disease. This recitation fails to further limit claims 5 and 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Philbrick et al (J Am. Soc. Nephrol., vol. 10, Sept. 1999, pp 85A; mailed to subscribers Aug. 26th, 1999). Philbrick et al disclose the reduction in cyst volumes in mice fed with group B soyasaponins has been withdrawn.

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Philbrick et al (J Am. Soc. Nephrol., vol. 10, Sept. 1999, pp 85A; mailed to subscribers Aug. 26th, 1999).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 16 are drawn to a method of treating kidney disease which is polycystic kidney disease.

(Philbrick et al drawn to effect of soyasaponin extract on polycystic kidney disease, disclose the reduction in cyst volumes in mice fed with group B soyasaponins. Group B soyasaponins as disclosed by Philbrick et al is seen to include soyasaponin B_b even though Philbrick et al do not teach a specific soyasaponin. Since soyasaponin B_b is present in the extract of Philbrick, the disclosure of Philbrick is a method of treating polycystic kidney disease.

Claim 16 is also rejected since it is the same as claim 1. It does not matter how the soyasaponin is obtained. The method of isolation is not accorded patentable weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the disclosure of Philbrick is a method of treating polycystic kidney disease.

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One of ordinary skill in the art would be motivated to do so in order to optimize the method of treatment of polycystic kidney disease.

The rejection of claims 9-12 and 14-15 are withdrawn in view of the arguments advanced by the applicants.

The rejections of Claims 5, 7, 17, 18, 19 and 20 ~~are rejected under~~ 35 U.S.C. 103(a) as being unpatentable over Philbrick et al (J Am. Soc. Nephrol., vol. 10, Sept. 1999, pp 85A; mailed to subscribers Aug. 26th, 1999) in combination with Shinohara et al (USPN 4217345) and Miyake et al (USPN 4557927) is being maintained for reason of record.

Philbrick et al drawn to effect of soyasaponin extract on polycystic kidney disease, disclose the reduction in cyst volumes in mice fed with group B soyasaponins. Group B soyasaponins as disclosed by Philbrick et al is seen to include soyasaponin B_b even though Philbrick et al do not teach a specific soyasaponin. Since soyasaponin B_b is present in the extract of Philbrick, the disclosure of Philbrick is a method of treating polycystic kidney disease.

Shinohara et al teach the use of a pharmaceutical composition containing an effective amount of soyasapogenol B and a pharmaceutically acceptable carrier for the treatment of nephritis (see col. 18, lines 1-20).

Miyake et al teach the use of alpha-glycosyl soyasaponins in sweeteners, chocolate, carbonated beverage and jelly (nutraceuticals, see cols. 15 and 16, examples 7, 11, 13 and 14).

Claims 5, 7, 17, 18, 19 and 20 are all composition claims comprising Since soyasaponin B_b. It does not matter how the soyasaponin B_b is obtained for it to be used as an active ingredient in a composition.

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Shinohara et al teaches pharmaceutical compositions containing an effective amount of soyasapogenol B. Philbrick teaches an alcohol enriched extract of soyasaponin which is seen to include soyasaponin B_b .

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical/nutraceutical composition based on the teachings of the prior art cited above, since compositions containing active ingredients which have the same structural core are taught in the prior art of record.

One ordinary skill in the art would be motivated to do so in order to optimize the amount of the active ingredient in the composition for the treatment as instantly claimed.

Claim 4 is objected to since it depends on a base claim which is rejected but would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

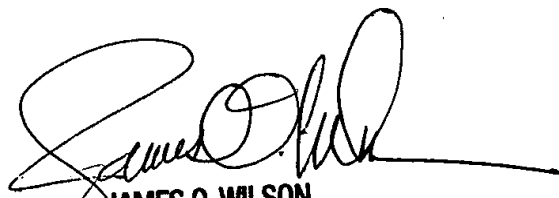
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837.

The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
April 7, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600